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10

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,176	07/08/2003	Taik Koo Yun	0662-0189P	6452
2292	7590	08/12/2004	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			COE, SUSAN D	
		ART UNIT	PAPER NUMBER	
		1654		

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/614,176	YUN ET AL.	
Examiner	Art Unit		
Susan D. Coe	1654		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 May 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

1. The amendment filed May 19, 2004, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 7-10 have been added.
3. Claims 1-10 are pending.

Claim Rejections - 35 USC § 112

4. Claims 1-6, 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are drawn to preventing cancer using "isolated ginsenosides" and reducing the occurrence of cancer using a composition "consisting essentially of ginsenosides." The claims are not considered to be enabled for these uses. This is technically a new ground of rejection based on applicant's inclusion of "isolated ginsenoside" and "consisting essentially of ginsenoside." However, this enablement issue was raised by the examiner in the previous Office action. Thus, applicant submitted arguments to support the enablement of the claims. All of

applicant's arguments regarding the enablement of the claims have been considered but are not deemed persuasive. Applicant argues that the claims are enabled for the prevention of cancer. Applicant states that the examiner is applying an improper standard by stating in the previous Office action that in order "to be enabled for prevention, applicant must show that the composition comprising the ginsenosides are able to prevent cancer in each and every possible occurrence of the cancer." Applicant states that the initial burden is on the examiner to show that the claims are not enabled. However, applicant is required to show that the claims work as claimed. A simple dictionary definition of "prevent" shows that this word means that a situation must be kept from occurring (see Merriam-Webster's Collegiate Dictionary (1997), 10th ed. page 924). Applicant clearly has not shown that the isolated ginsenosides are able to keep cancer from occurring. Applicant's specification has one experiment with rats that attempts to show the cancer preventive effects of ginsenosides (Experiment 1). This experiment shows a reduction in the amount of cancers, but a significant number of rats given the carcinogen in combination with the ginsenoside still contract cancer. Thus, applicant's own specification shows that the ginsenosides do not prevent cancer.

Applicant also argues that the use of the word "prevention" in the Yun et al. article shows that this term is an acceptable term in the art. Applicant states that "it is recognized in the art that cancer can, **to some extent**, be prevented (emphasis added)." However, as discussed above, for patentability standards, the dictionary definition of "prevent" is applied. Prevention "to some extent" is not considered to be a proper showing of "prevention."

Applicant also argues that Experiment 1 shows that the ginsenosides are able to reduce the occurrence of cancer. However, applicant's experiment only shows the reduction of specific types of cancer using rats as model while applicant's claims are broadly drawn to reducing in type of cancer in any patient. Thus, applicant's claims encompass treating humans. Prior art such as Gorman and Golden (Time Magazine (1998), vol. 151, no. 19, pp. 38-44) and Gura (Science (1997), vol. 278, pp. 1041 and 1042) show that it is known in the art that rodent models are not considered to be predictive of human treatment. On page 44, Golden discusses that research scientists in the cancer community acknowledge that "most drugs that work in lab animal turn out to be duds in human." Gura similarly quotes cancer drug researchers as stating "that the fundamental problem in drug discovery for cancer is that the model systems are not predictive at all (see page 1041, first column, second paragraph)." Thus, due to the unpredictability of applying rodent results to human treatment, a person of ordinary skill in the art would be forced to experiment unduly in order to ascertain if the claimed invention can function as claimed in any patient other than in the rat model used.

Claim Rejections - 35 USC § 102

5. Claims 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Yun et al. (Cancer Epidemiol. Biomarkers & Prev. (1995), vol. 4, pp. 401-408) for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that Yun does not anticipate the claims because Yun does not teach reducing the occurrence of cancer using a composition comprising

ginsenosides as the active ingredient. However, Yun is treating the same patient with the same composition, a composition that comprises ginsenoside. Thus, Yun meets every positive limitation of the claim, the same patient is in contact with the same composition for the same overall purpose. Therefore, the ginsenosides in the composition of Yun must be the active ingredient if applicant's invention functions as claimed.

Applicant also argues that Yun does not show prevention but only reduction in the occurrence of cancer. Claims 7 and 8 are directed to reduction in the occurrence and not to prevention. Thus, Yun is still considered to anticipate the stated claims.

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Susan D. Coe, Examiner
August 3, 2004